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EXAMINER	
DOUGHERTY, SEAN PATRICK	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,139	CHANNER ET AL.	
	Examiner	Art Unit	
	SEAN P. DOUGHERTY	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the *FINAL* Office action based on the 10/587139 application filed April 5, 2007. Claims 1-9, as originally filed, are currently pending and have been considered below and claim 10 has been cancelled. Claim 1 independent.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5 & 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Tripp et al. (US 6,186,960 B1).

Regarding claim 1, Tripp et al. discloses a blood collection device comprising:

a housing (tubular body, Fig. 2 #12) having an open rear end adapted to accommodate an evacuated blood collecting tube (collection tube holder, Fig. 2 #12; "inserts an evacuated test tube into the interior of the collection tube holder" Col. 3, lines 7-9) and a front end (distal end, Fig. 2 #32), a needle holder in the front end (needle port hub, Fig. 2 #14), a needle which is attached to the needle holder ("the needle port hub in turn accepts a bi-directional needle" Col. 2, lines 59-60) and which is double ended ("bi-directional needle" Col. 3, line 2) and has a first end (outer end) that projects from the housing and a second end (inner end) that projects into the housing ("one needle end is exposed to the exterior environment and the other needle end is contained within the interior of the collection tube holder" Col. 3 lines 3-6), the needle

holder being releasably attached relative to the housing ("detachable needle port hub" Col. 2 lines 61-63) to enable the needle holder and the attached needle to be retracted ("needle port hub with affixed needle … drawn into the interior of the evacuated accessory" Col. 3 lines 56-60), and a needle retraction device (evacuated accessory, Fig. 4 #18), the needle retraction device able to be pushed into the housing ("tubular member with an evacuated interior is inserted into the collection tube holder fully" Abstract, lines 15-16) to release the needle holder from the housing and to retract the needle holder containing the attached needle into the needle retraction device ("needle port hub with affixed needle … drawn into the interior of the evacuated accessory" Col. 3 lines 56-60), wherein the needle holder contains at least one finger member that engages relative to the housing to retain the needle holder to the housing, the finger member being deflectable between a locking position where the finger member retains the needle holder to the housing (hub release ring, Fig. 2 #16; "detachable needle port hub is secured within the interior of the collection tube holder at the distal end by a hub release ring that is wedged between the detachable needle port hub and the interior wall of the holder" Col. 2, lines 61-65), and a release position where the needle holder can be retracted into the housing ("the retaining ring holding the combination part within the accessory chamber release[s] from the needle port hub and advance[s] [the needle port hub] into the annular channel" Col. 3, lines 53-55).

Regarding claim 2, Tripp et al. discloses a blood collection device wherein:

the needle holder comprises an assembly of at least two parts, the first part being an inner part (male needle holder, Fig. 2 #46) and containing a passageway through

which a puncture needle can extend to fit the puncture needle to the inner part (Fig. 2 discloses a puncture needle [bidirectional needle #48] extending to fit to an inner part [male needle holder #46]), the second part comprising an outer nosepiece (threaded female orifice, Fig. 2 #44), the at least one finger member being attached relative to the nosepiece (Fig. 2 discloses a finger member [hub release ring #16] attached relative to an outer nosepiece [threaded female orifice #48]).

Regarding claim 3, Tripp et al. discloses a blood collection device wherein:

the needle retraction device comprises an elongate hollow body (tubular member, Fig. 4 #30; hollow chamber, Fig. 4 #70) which contains a vacuum ("capable of holding a vacuum" Col. 5, line 34; "the [needle retraction device] has an air release/vacuum seal mechanism that permits the introduction and retention of negative pressure within the chamber" Col. 3, lines 22-24) and which has an open end (open distal end, Fig. 4 #62), a piston which closes off the open end of the elongate hollow body (combination part, Fig. 4 #20) and which is adapted for sliding movement within the hollow body, and which is releasably attached relative to the open end ("combination part #20 moves[s] axially within tubular member 30" Col. 6, lines 36-37).

Regarding claim 4, Tripp et al. discloses a blood collection device wherein:

the piston comprises at least one finger member (catch ring, Fig. 4 #24; retaining ring, Fig. 4 #28) which releasably attaches the piston relative to the one end of the hollow body, the finger member being movable between a locking position where the piston is attached to the hollow body ("axial force applied to … evacuated accessory causes the catch ring portion to begin to mate with the detachable needle port hub and

affixed needle" Col. 3, lines 43-46), and a release position where the piston can be retracted into the hollow body under the influence of the vacuum ("axial force applied on … evacuated accessory ... causes retaining ring holding the combination part … [to be] … released to the action of the negative pressure … and the complex is drawn into the interior of the evacuated accessory." Col. 3, lines 51-60).

Regarding claim 5, Tripp et al. discloses a blood collection device wherein:

at least one finger member on the piston extends forwardly from the piston ("axially extending catch ring 24" Col. 6, lines 29-30; retaining ring, Fig. 4 #28), and the at least one finger member on the needle holder extends rearwardly (hub release ring, Fig. 2 #16) such that as the needle retraction device is pushed against the rear of the needle holder ("tubular member with an evacuated interior is inserted into the collection tube holder fully" Abstract, lines 15-16), the at least one finger member on the piston releases the at least one finger member on the needle holder, and engages to the at least one finger member on the needle holder ("the catch ring portion of the combination part … caus[es] the hub release ring holding the needle port hub within the collection tube holder to release from the needle port hub" Col. 3, lines 43-50).

Regarding claim 9, Tripp et al. discloses a blood collection device wherein:

a housing (tubular body, Fig. 2 #12) having an open rear end adapted to accommodate an evacuated blood collecting tube (collection tube holder, Fig. 2 #12; "inserts an evacuated test tube into the interior of the collection tube holder" Col. 3, lines 7-9), and a front end(distal end, Fig. 2 #32), a needle holder in the front end (needle port hub, Fig. 2 #14), a needle which is attached to the needle holder ("the needle port

hub in turn accepts a bi-directional needle" Col. 2, lines 59-60) and which is double ended ("bi-directional needle" Col. 3, line 2) and has a first end (outer end) that projects from the housing and a second end (inner end) that projects into the housing ("one needle end is exposed to the exterior environment and the other needle end is contained within the interior of the collection tube holder" Col. 3 lines 3-6), the needle holder being releasably attached relative to the housing ("detachable needle port hub" Col. 2 lines 61-63) to enable the needle holder and the attached needle to be retracted ("needle port hub with affixed needle … drawn into the interior of the evacuated accessory" Col. 3 lines 56-60), wherein the needle holder contains at least one finger member that engages relative to the housing to retain the needle holder to the housing, the finger member being deflectable between a locking position where the finger member retains the needle holder to the housing (hub release ring, Fig. 2 #16; "detachable needle port hub is secured within the interior of the collection tube holder at the distal end by a hub release ring that is wedged between the detachable needle port hub and the interior wall of the holder" Col. 2, lines 61-65), and a release position where the needle holder can be retracted into the housing ("the retaining ring holding the combination part within the accessory chamber release[s] from the needle port hub and advance[s] [the needle port hub] into the annular channel" Col. 3, lines 53-55).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tripp et al. (US 6,186,960 B1) in view of Kaufhold et al. (US 5,000736 A).

Regarding claim 6, Tripp et al. discloses a blood collection device wherein:

there is a housing (tubular body, Fig. 2 #12), the housing contacting the at least one finger member on the piston ("operator inserts the evacuated accessory … pushing completely into the collection tube holder" Col. 3, lines 40-43; the Examiner notes Fig. 6 discloses the one finger member in contact with the housing) when the needle retraction device is pushed against the rear of the needle holder ("tubular member with an evacuated interior is inserted into the collection tube holder fully" Abstract, lines 15-16), the at least one finger member releases the at least one finger member from engagement with the hollow body to enable the piston containing the attached needle holder to be retracted into the hollow body under the influence of vacuum ("the catch ring portion of the combination part … caus[es] the hub release ring holding the needle port hub within the collection tube holder to release from the needle port hub" Col. 3, lines 43-50).

Tripp et al. does not appear to explicitly disclose a blood collection device wherein:

the housing is provided a ramp in a forward portion of the housing, the ramp contacting the at least one finger member on the piston when the needle retraction device is pushed against the rear of the needle holder, the at least one finger member riding along the ramp to release the at least one finger member from

engagement with the hollow body to enable the piston containing the attached needle holder to be retracted into the hollow body under the influence of vacuum.

However, ***Kaufhold et al. teaches*** a blood collection device wherein:

the housing is provided a ramp (taper d, Fig. 7) in a forward portion of the housing, the ramp contacting the at least one finger member on the piston when the needle retraction device is pushed against the rear of the needle holder, the at least one finger member riding along the ramp to release the at least one finger member from engagement with the hollow body to enable the piston containing the attached needle holder to be retracted into the hollow body under the influence of vacuum.

Tripp et al. and Kaufhold et al. are analogous art because they are from the same field of endeavor/problem solving area of disposable medical collection tube holder assemblies with retractable needles. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Tripp et al. and Kaufhold et al. before him or her to modify the housing of Tripp et al. to include the ramp Kaufhold et al. The Examiner notes that this is simple substitution of the housing of Tripp et al. to include the ramp of Kaufhold et al. to obtain the predictable result of the at least one finger on the piston to ride along the ramp to release the at least one finger member from the engagement with the hollow body to enable the piston to retract into the hollow body. The Examiner notes that the finger as disclosed in Tripp et al. already rides along the housing of Tripp et al. to engage and release the piston into the hollow body; adding the ramp as taught in Kaufhold et al. simply modifies the housing of Tripp et al., obtaining the same result of the release of the piston into the hollow body. The

suggestion/motivation for doing so would have been to "provide a disposable medical collection tube holder with retractable needle" (Col. 3, lines 65-67) as disclosed by Tripp et al., to "provide a disposable medical collection tube holder with retractable needle that allows safe disposal of used needles when used with a companion evacuated accessory" (Col. 4, lines 1-4) as also disclosed by Tripp et al. and to "provid[e] a means of automatically, without the need of unusual manipulation, rendering a used syringe safe for handling immediately after use" (Col. 1, lines 65-67) as taught by Kaufhold et al. Therefore, it would have been obvious to combine Tripp et al. with Kaufhold et al. to obtain the invention in the instant claim 6.

Claim 7 is is rejected under 35 U.S.C. 103(a) as being unpatentable over Tripp et al. (US 6,186,960 B1) in view of Daley et al. (US 6,572,565 B2).

Regarding claim 7, Tripp et al. discloses a blood collection device wherein:

a piston (combination part, Fig. 4 #20) and a needle retraction device (evacuated accessory, Fig. 4 #18) that are pushed against the rear of the needle holder ("tubular member with an evacuated interior is inserted into the collection tube holder fully" Abstract, lines 15-16).

Tripp et al. does not appear to explicitly disclose a blood collection device wherein:

the piston contains a pierceable material that is pierced by the inner end of the needle when the needle retraction device is pushed against the rear of the needle holder to seal the inner end of the needle.

However, ***Daley et al. teaches*** a blood collection device wherein:

the piston contains a pierceable material that is pierced by the inner end of the needle when the needle retraction device is pushed against the rear of the needle holder to seal the inner end of the needle ("The vial is inserted into the extractor end of the cylinder 10 so that the posterior end 30 of the needle 26 pierces through a stopper or membrane in the vial" Col. 5, lines 31-34; Fig. 2 discloses the inner end of the needle [posterior end] #30 sealed by the pierceable material [stopper] #66).

Tripp et al. and Daley et al. are analogous art because they are from the same field of endeavor/problem solving area of disposable medical collection tube holder assemblies with retractable needles. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Tripp et al. and Daley et al. before him or her to modify the piston of Tripp et al. to include the pierceable material of Daley et al. The Examiner notes that the combination of the piston and the pierceable member is simply combining prior art elements according to known methods to yield predictable results. The Examiner additionally notes that this is applying a known technique to a known device ready for improvement to yield predictable results. At the time of the invention, it would have been obvious to one of ordinary skill in the art, to modify the piston disclosed by Tripp et al. by adding the pierceable member taught by Daley et al. to be pierced by the inner end of the needle when the needle retraction device is pushed against the rear of the needle holder to seal the inner end of the needle. The suggestion/motivation for doing so would have been to "provide a disposable medical collection tube holder with

retractable needle" (Col. 3, lines 65-67) as disclosed by Tripp et al., to "provide a disposable medical collection tube holder with retractable needle that allows safe disposal of used needles when used with a companion evacuated accessory" (Col. 4, lines 1-4) as also disclosed by Tripp et al. and to "provide an improved blood sampling assembly for retracting a needle and needle seat from a cylinder and thereby shielding the needle after completion of a blood collection procedure" (Col. 3, lines 44-47) as taught by Daley et al. Therefore, it would have been obvious to combine Tripp et al. with Daley et al. to obtain the invention in the instant claim 7.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tripp et al. (US 6,186,960 B1) in view of Vallenlunga et al. (US 5,352,203 A).

Regarding claim 8, Tripp et al. discloses a blood collection device comprising:

a piston (combination part, Fig. 4 #20) that retracts into a hollow body ("combination part #20 moves[s] axially within tubular member 30" Col. 6, lines 36-37) .

Tripp et al. does not appear to explicitly disclose a blood collection device wherein:

the piston contains a speed controller to control a speed of retraction of the piston into the hollow body, the speed controller comprising a sealing member extending from the piston and sealingly engaging with the hollow body to increase the frictional force of the piston on the hollow body.

However, Vallenglunga et al. teaches a blood collection device wherein:

the piston contains a speed controller to control a speed of retraction of the piston into the hollow body, the speed controller comprising a sealing member extending from the piston and sealingly engaging with the hollow body to increase the frictional force of the piston on the hollow body ("The second connecting member includes a plurality of protrusions 28 which extend radially away from a second aperture 27 to form a friction fit within the inner diameter of an outer housing" Col. 4, lines 10-14).

Tripp et al. and Vallenlunga et al. are analogous art because they are from the same field of endeavor/problem solving area of disposable medical collection tube holder assemblies with retractable needles. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Tripp et al. and Vallenlunga et al. before him or her to modify the plunger of Tripp et al. to include the sealing members extending from the piston and sealing engaging with the hollow body providing a friction force of Vallenlunga et al. The Examiner notes that the combination of the piston and the sealing members is simply combining prior art elements according to known methods to yield predictable results. The Examiner additionally notes that this is use of a known technique to improve similar devices in the same way. At the time of the invention, it would have been obvious to one of ordinary skill in the art, to modify the plunger to include sealing members along the walls to provide friction. It is known to one of ordinary skill in the art that a plurality of protrusions along the plunger to form a friction fit with an inner diameter would obtain the predictable result of creating friction acting as a speed controller. The suggestion/motivation for doing so would have been to "provide a disposable medical collection tube holder with retractable needle" (Col. 3,

lines 65-67) as disclosed by Tripp et al., to "provide a disposable medical collection tube holder with retractable needle that allows safe disposal of used needles when used with a companion evacuated accessory" (Col. 4, lines 1-4) as also disclosed by Tripp et al. and to a "plunger for a non-reusable syringe … capable of aspirating fluids" (Col. 1, lines 5-9) and to provide "a non-reuseable syringe which becomes inoperative or incapable of further use automatically without an additional act on the part of the user" (Col. 1, lines 42-45) as disclosed by Vallenlunga et al. Therefore, it would have been obvious to combine Tripp et al. with Vallenlunga et al. to obtain the invention in the instant claim 8.

Response to Arguments

Applicant's amendments have overcome the drawing, specification and 112 second paragraph rejections from the previous Office Action.

Applicant's arguments filed February 6, 2008 have been fully considered but they are not persuasive as discussed below.

Applicant argues on page 8 that Tripp et al does not teach a finger member and that a finger member would be in no way analogous to a release ring. The Examiner disagrees.

The Applicant's arguments do not commensurate in scope with the claimed invention. While the claimed invention provides functional language regarding the

“finger member”, the claimed invention does not provide sufficient structural limitations of the "finger member" to suggest that a finger member is not equivalent to a release ring, thus a structural difference between a “finger member” and a “release ring" member cannot be positively ascertained.

Furthermore, the ring of Tripp et al meets the functional limitations of the claimed subject matter, as the release ring is deflectable between a locking position where the release ring retrains the needle holder to the housing (best seen in Fig. 6), and a release position where the needle holder can be retracted into the housing (best seen in Fig. 7).

Applicant argues on page 8 that the release ring taught in Tripp et al does not “engage relative to the housing” as recited in claims 1 and 9. The Examiner disagrees.

As best seen in Fig. 6 and Fig. 7, the release ring [16] of Tripp et al engages relative to the housing as it is pushed by combination part [20] and contacts against body [12].

Applicant argues on page 8 that release ring is not “delectable” because it is not "capable of being bent or turned aside". The Examiner disagrees.

Regarding the term "deflectable", applicant is apparently invoking his rights as an inventor to be his own lexicographer, arguing that he defined "deflectable" in the specification in a way that requires specific limitations to be read into the term. Although a patentee may be his own lexicographer, the patent specification must

support his asserted definition. Applicant did not explicitly define terms anywhere in the specification in ways that support his current assertions. The text does not implicitly suggest that the words should be interpreted to convey the restricted interpretation that he now asserts.

Applicant argues on pages 8-9 that the Examiner failed to recognize the advantages over the device taught by Tripp et al. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Lastly, Examiner argues on pages 9-10 that claims 6-8 depend on claim 1, and as discussed by the Applicant, Tripp et al does not disclose all of the elements recited in the claimed invention, thus the *prima facie* obviousness does not exist. The Examiner disagrees and points to response to arguments above indicating that Tripp et al does disclose all of the elements of the claimed invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean P. Dougherty whose telephone number is (571) 270-5044. The examiner can normally be reached on Monday-Thursday, 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on (571) 272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. P. D./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736